July 15, 1999

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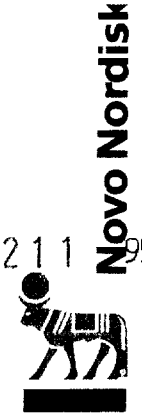

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers lane, rm. 10611
Rockville, MD 20852

Re: Comments on [FR DOC. 99-0674]

To Whom it may concern:

Submitted in duplicate are comments on the Draft Guidance for Industry, "INDs for Phase 2 and 3 Studies of Drugs, including Specified Therapeutic Biotechnology - Derived Products - Chemistry, Manufacturing, and Controls Content and Format" for your consideration.

In line 304 of the document it states, ... *"Stress testing (e.g., photostability) on the drug product should be conducted"*.

We believe that it is too early to perform photostability on the drug product at this development stage and request removal of this statement.

In line 433 and line 537 it is stated, *"the stability protocol should include a description of the ~~drug~~ product under... "*.

We would suggest being more specific as to what is being requested (i.e.- quantitative composition, description of drug class and/or delivery system [chemotherapeutic agent, transdermal patch, etc.]).

If you have any questions, please contact me at (609) 987-5940 or by telefax (609) 987-3916,

Sincerely,

Timothy Urschel

Timothy Urschel
Assistant Director
Regulatory Affairs

99D-0674

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